DETAILED ACTION

Applicants amendment filed February 26, 2010 has been received and entered. Claims 1-2, 8, 11-19, 21, 23-44, 46-49, 53, 61-81, 84, 89, 91-95, 97, 99-113, 116, 119, 122, 127, and 131 have been cancelled, and new claims 133-142 have been added. Accordingly, claims 3-7, 9-10, 20, 22, 45, 50-52, 54-60, 82-83, 85-88, 90, 96, 98, 114-115, 117-118, 120-121, 123-126, 128-130, and 132-142 are pending in the instant application.

It is noted that Applicants arguments filed February 26, 2010 assert that claims 17 and 89 are pending, however both claims 17 and 89 have been cancelled by Applicants.

Claim Rejections - 35 USC § 112

1. The rejection of claims 61, 127 and 131 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions, does not reasonably provide enablement for vaccine compositions is withdrawn in view of the cancellation of said claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year

prior to the date of application for patent in the United States.

2. The rejection of claims 3-7, 9-10, 20, 22, 45, 50-52, 54-60, 82-83, 85-88, 90, 96, 98, 114-115, 117-118, 120-121, 123-126, 128-130, and 132 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Berthet et al is maintained. Additionally this rejection is applied to newly added claims 133-142.

Applicants are asserting that claims 117, 120 and 123 (from which all other claims depend) are directed to immunogenic compositions comprising at least 3 different antigens selected from at least 3 different categories of Neisserial antigens. Applicants further assert that Berthet et al does not teach that the preparation should have at least 3 different antigens, where each antigen is selected from one of 3 different antigen classes as recited in claims 117, 120 and 123. Applicants finally assert that Berthet teaches a large genus of possible antigen combinations, in fact claim 15 of Berthet encompasses 7980 possible combinations containing three different antigens.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that claims 117, 120 and 123 (from which all other claims depend) are directed to immunogenic compositions comprising at least 3 different antigens selected from at least 3 different categories of Neisserial antigens. However, Applicants arguments are not commensurate in scope with Applicants claim language. For example, claim 117 recites "comprising at least one Neisserial autotransporter antigen, at least one Neisserial adhesin antigen and at least one different antigen…"

The autotransporter antigens are selected from Hsf, Hap, IgA protease, AspA and NadA. The Neisserial adhesion antigen is selected from FhaB, NspA, PilC, Hsf, Hap, MafA, MafB, Omp26, NMB0315, NMB0995, NMB1119 and NadA. The one different antigen is selected from an extensive list of 49 distinct molecules. Applicants attention is directed to the fact that the list of autotransporter antigens and adhesion antigens contains significant overlap. For example Hsf, Hap and NadA are listed as both autotransporters and adhesion antigens. Consequently, the presence of any of Hsf, Hap, or NadA in a composition would meet the limitations of "containing at least one Neisserial autotransporter antigen and at least one Neisserial adhesion antigen." There is no claim limitation, and indeed the claim language would directly refute the assertion that the Neisserial Autotransporter antigen and Neisserial adhesion antigen must be different.

Second, Applicants assert that Berthet et al does not teach that the preparation should have at least 3 different antigens, where each antigen is selected from one of 3 different antigen classes as recited in claims 117, 120 and 123. However, as recited above, Applicants claims do not require at least 3 different antigens. Furthermore, claim 15 of Berthet et al clearly set forth that “one ***or more*** genes are upregulated” and specifically include Hsf, Hap and FrpA; the precise combination required by the instant claims. (Emphasis added).

Finally, Applicants assert that Berthet teaches a large genus of possible antigen combinations, in fact claim 15 of Berthet encompasses 7980 possible combinations containing three different antigens. Applicants appear to believe that their own claims

are somehow a narrow species. Applicants will hopefully appreciate that while Berthet teaches 21 antigens which can be upregulated, Applicants instant claims recites a total of 66 antigens (claim 117) from which 3 (as alleged; or possibly 2 as read by the Examiner) are selected. Applicants instant claims are in fact a much larger genus than the disclosure of Berthet et al. Accordingly, Applicants arguments are not persuasive.

The claims are directed to an immunogenic composition comprising at least one Neisserial autotransporter antigen, at least one Neisserial adhesion antigen and at least one different antigen, wherein each of said antigens is isolated or enriched, and wherein the at least one different antigen is selected from Neisserial toxin antigens, Neisserial Iron acquisition proteins and Neisserial membrane associated proteins.

Berthet et al (WO 2001/009350) disclose of immunogenic compositions comprising Nesisserial enriched antigens Hsf, OMP85, TbpA, TbpB, FrpA and FrpC. (See abstract and claims; specifically claim 15).

Given that Hsf is a Neisserial autotransporter antigen and a Neisserial adhesion antigen (See claim 117 of instant specification) and that FrpA is a Neisserial toxin, the disclosure of Berthet et al is deemed to anticipate the instantly filed claims.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. The rejection of claims 3-7, 9-10, 20, 22, 45, 50-52, 54-60, 82-83, 85-88, 90, 96, 98, 114-115, 117-118, 120-121, 123-126, 128-130, and 132 as being unpatentable over claims 1-57 and 60-71 of copending Application No. 10/523,114 is maintained. Additionally this rejection is applied to newly added claims 133-142. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims encompasses immunogenic compositions of Neisserial Hsf and Tbp.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that Applicants will address the rejections with respect to the remaining

claims at such time as the claims of 10/523,114 are deemed allowable.

Accordingly this rejection is maintained for reasons of record.

4. The rejection of claims 3-7, 9-10, 20, 22, 45, 50-52, 54-60, 82-83, 85-88, 90, 96, 98, 114-115, 117-118, 120-121, 123-126, 128-130, and 132 as being unpatentable over claims 1-8, 14-20, 53, and 59-60 of copending Application No. 10/523,044 is maintained. Additionally this rejection is applied to newly added claims 133-142.

Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims encompasses immunogenic compositions of Neisserial Hsf and OMP85.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that Applicants will address the rejections with respect to the remaining claims at such time as the claims of 10/523,044 are deemed allowable.

Accordingly this rejection is maintained for reasons of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
March 30, 2010